

ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NIGHT- aspirin, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine bitartrate tablet, effervescent
Bayer HealthCare LLC.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Alka-Seltzer Plus Severe Cold Powerfast Fizz UI 1614458

Drug Facts

Active ingredients (in each tablet) Purposes

Aspirin 500 mg (NSAID)*.....Pain reliever/fever reducer

Dextromethorphan hydrobromide 10 mg.....Cough suppressant

Doxylamine succinate 6.25 mg.....Antihistamine

Phenylephrine bitartrate 7.8 mg.....Nasal decongestant

*nonsteroidal anti-inflammatory drug

Uses

Uses

- temporarily relieves these symptoms due to a cold:
- minor aches and pains • headache • runny nose
- sinus congestion and pressure • cough • sneezing
- sore throat • nasal congestion
- temporarily reduces fever

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives • facial swelling • asthma (wheezing) • shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients
- in children under 12 years of age

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have
- asthma • diabetes • thyroid disease • glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a sodium-restricted diet

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for
- gout • diabetes • arthritis
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness

- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
- feel faint • vomit blood • have bloody or black stools
- have stomach pain that does not get better
- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- ringing in the ears or a loss of hearing occurs
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.
- nervousness, dizziness, or sleeplessness occurs

If pregnant or breast-feeding, ask a health professional before use.

It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions

- adults and children 12 years and over: take 2 tablets fully dissolved in 4 oz of water every 6 hours. Do not exceed 8 tablets in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

Other information

- each tablet contains: potassium 80 mg; sodium 356 mg
- store at room temperature. Avoid excessive heat.

Inactive ingredients anhydrous citric acid, calcium silicate, dimethicone, flavors, mannitol, potassium bicarbonate, povidone, sodium bicarbonate, sucralose

Questions or comments?

Questions or comments? 1-800-986-0369 (Mon-Fri 9AM - 5PM EST)

Alka-Seltzer

PLUS®
SEVERE
Cold
POWERFAST FIZZ™ NEW IMPROVED FLAVOR
NIGHT

ASPIRIN(NSAID) / Pain Reliever-Fever Reducer
Dextromethorphan HBr / Cough Suppressant
Doxylamine Succinate / Antihistamine
Phenylephrine Bitartrate / Nasal Decongestant

- Nasal Congestion
- Headache + Body Ache
- Cough
- Runny Nose
- Sore Throat

20 EFFERVESCENT TABLETS



ALKA-SELTZER PLUS SEVERE COLD POWERFAST FIZZ NIGHT
aspirin, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine bitartrate tablet, effervescent

| Product Information | | | |
|--|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0280-0021 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E) | | ASPIRIN | 500 mg |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) | | DEXTROMETHORPHAN | 10 mg |

| | | |
|--|--------------------------|---------|
| (DEXTROMETHORPHAN - UNII:7355X3ROTS) | HYDROBROMIDE | 10 mg |
| PHENYLEPHRINE BITARTRATE (UNII: 27O3Q5ML57) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE BITARTRATE | 7.8 mg |
| DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 6.25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| CALCIUM SILICATE (UNII: S4255P4G5M) | |
| DIMETHICONE (UNII: 92RU3N3YIO) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| POTASSIUM BICARBONATE (UNII: HM5Z15LEBN) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | no score |
| Shape | ROUND | Size | 25mm |
| Flavor | LEMON | Imprint Code | ASP;NT |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0280-0021-01 | 10 in 1 CARTON | 04/01/2020 | |
| 1 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part341 | 04/01/2020 | |

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 4/2020

Bayer HealthCare LLC.